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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,308	08/21/2003	Paul B. J. Burton	3432-US-NP	9578
22932	7590	07/30/2007		
IMMUNEX CORPORATION LAW DEPARTMENT 1201 AMGEN COURT WEST SEATTLE, WA 98119			EXAMINER JIANG, DONG	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 07/30/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/646,308	<b>Applicant(s)</b> BURTON ET AL.	
	<b>Examiner</b> Dong Jiang	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 31-62 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's election with traverse of Group II invention filed on 10 May 2007 is acknowledged. Applicant's species election of 4-1BBL antibody, cardiomyopathy, amsacrine, and doxorubicin, filed on 10 May 2007 is acknowledged.

Upon further consideration, the restriction requirement (species election, part C, 2.) made in the last Office Action mailed on 4/10/07 is improper for the following reason: the agents recited in claim 48 (5 agents), and in claim 53 (14 agents) are all chemotherapeutic agents, and both claims are dependent from claim 46. Therefore, all 19 chemotherapeutic agents should be grouped in one group for species election, instead separated groups (part C, 2., and part D). As such, a supplemental restriction requirement is warranted to correct this error, and applicant's election filed on 10 May 2007 is moot. The following restriction requirement supersedes the one mailed on 4/10/07.

Currently, claims 31-62 are pending.

#### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 31-45, drawn to a method of treating a cardiovascular disease with a 4-1BB antagonist, classification depending upon the chemical entity of the antagonist.
- II. Claims 46-55, drawn to a method for reducing chronic cardiotoxicity with a 4-1BB antagonist, classification depending upon the chemical entity of the antagonist.
- III. Claims 56-62, drawn to a method for treating cancer with a 4-1BB antagonist, classification depending upon the chemical entity of the antagonist.

The inventions are distinct, each from the other because:

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Inventions I-III are distinct each from each other because they are the methods of treating different medical conditions, which are caused by distinct pathogens and therefore, involve distinct patient populations, have distinct clinical manifestations, distinct features in progress and prognosis, and require different therapies. Therefore, each group requires a separate search of the prior art.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

**Species Election**

A. If group I is elected, a further elections of species is required:

1. This application contains claims directed to the following patentably distinct species: there are more than 30 different clinical diseases/conditions recited in claim 31. The species are independent or distinct because the recited diseases/conditions have distinct pathology, clinical manifestations, and distinct features in progress and prognosis, and involve distinct patient populations and different therapies, and thus, each requires a separate search of the prior art.

2. This application further contains claims directed to the following patentably distinct species: there are more than 8 different types of drugs recited in claim 43, which can be used in combination with the 4-1BB antagonist in the method, and they are: non-steroidal anti-inflammatory cytokines; chemotherapeutics; lipid-lowering drugs; blood pressure-regulating drugs; angiotensin-converting enzyme inhibitors; antibiotics; corticosteroids; and peroxisome proliferator-activated receptor ligands. The species are independent or distinct, each from each other, because they are distinct chemical entities sharing neither structure nor function, and therefore, each requires a separate search of the prior art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of groups 1 and 2 above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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B. If any one of groups I-III set forth above is elected, a further election of species is required:

This application contains claims directed to the following patentably distinct species: there are three 4-1BB antagonists recited in claims 32, 34, 50 and 58, and they are: a soluble 4-1BB; an antibody that specifically binds 4-1BB; and an antibody that specifically binds 4-1BB-L. The species are independent or distinct, each from each other, because they are structurally distinct chemical entities, and therefore, each requires a separate search of the prior art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

C. If group II is elected, a further election of species is required:

1. This application contains claims directed to the following patentably distinct species: there are 5 different clinical diseases/conditions recited in claim 47, and they are: arrhythmia, myocarditis, pericarditis, myocardial infarction and cardiomyopathy. The species are independent or distinct because the recited diseases/conditions have distinct pathology, clinical manifestations, and distinct features in progress and prognosis, and involve distinct patient populations and different therapies, and thus, each requires a separate search of the prior art.

2. This application further contains claims directed to the following patentably distinct species: there are 19 different types of chemotherapeutic agents recited in claim 48 (five) and claim 53 (fourteen). The species are independent or distinct, each from each other, because they are distinct chemical entities sharing neither structure nor function, and therefore, each requires a separate search of the prior art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of groups 1 and 2 above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

D. If group III is elected, a further election of species is required:

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This application contains claims directed to the following patentably distinct species: there are 5 anthracycline drugs recited in claim 57, and they are: doxorubicin, daunorubicin, epirubicin, idarubicin and mitroxantrone. The species are independent or distinct, each from each other, because they are structurally distinct chemical entities, and therefore, each requires a separate search of the prior art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention and a species (or more as applicable) to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

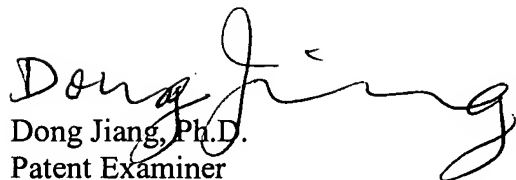
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**Advisory Information**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Dong Jiang, Ph.D.  
Patent Examiner

AU1646

7/23/07